

**INFORMATION TO BE SUBMITTED TO FDA BY PROSPECTIVE THIRD PARTIES  
SEEKING FDA RECOGNITION FOR REVIEW OF SELECTED 510(k)s:  
A CHECKLIST**

**ADMINISTRATIVE INFORMATION**

- 1) Name and address of Third Party
- 2) Phone Number and Fax Number of contact person
- 3) Name and title of the most responsible individual at the third party firm
- 4) Brief description of third party including: type of organization (e.g. not-for-profit institution, business, other type of organization); size of organization (number of employees); number of years in operation; nature of work (e.g. testing or certification laboratory, etc.); and information regarding ownership, operation, and control of organization sufficient to assess its degree of independence from device manufacturers and distributors.
- 5) List any Federal, State, local, or other accreditations.
- 6) Identify the devices the third party seeks to review. Clearly identify the devices by classification name and citation in 21 CFR 862-892, or by classification panel if seeking to review a subset of eligible devices.
- 7) For third parties located outside the United States:  
Name and address of authorized representative in U.S.  
Phone Number and Fax Number

**PREVENTION OF CONFLICTS OF INTEREST**

- 8) A copy of the written policies and procedures established by the third party to ensure that it and its employees involved in the third-party review of 510(k)s are free from conflicts of interest, and to ensure prevention of any individual or organizational conflict of interest or appearance of conflict of interest that might affect the review process.

FDA will assess these written policies and procedures to ensure that the most common conditions that indicate a potential conflict of interest are addressed and that:

- a. The third party is not owned, operated, or controlled by a device manufacturer or distributor.
- b. Neither the third party nor any of its personnel involved in 510(k) reviews have any ownership or other financial interest in any medical device, device manufacturer, or distributor.
- c. Neither the third party nor any of its personnel involved in 510(k) reviews participate in the design, manufacture, or distribution of any medical device.
- d. Neither the third party nor any of its personnel involved in 510(k) reviews provide consultative services to any device manufacturer or distributor regarding any specific devices (e.g. regarding the preparation of IDEs, PMAs or quality assurance consultation for the purpose of complying with GMPs).

- e. Neither the third party nor any of its personnel involved in 510(k) reviews participate in the preparation of any 510(k).
- f. The fee charged or accepted by the third party is not contingent or based upon the type of recommendation made by the third party.

## **FACILITIES**

- 9) Identify the equipment the third party has for interfacing with FDA's electronic data systems (e.g., computer system with a modem, an independent facsimile).

## **PERSONNEL QUALIFICATIONS**

- 10) FDA will consider several factors with respect to personnel qualifications and the preparedness of the third party to conduct technically competent reviews at the time of requesting recognition by FDA. These factors include:
  - a. The written policies and procedures established to ensure that 510(k)s are reviewed by qualified personnel.
  - b. The written instructions for the duties and responsibilities of third party personnel with respect to 510(k) reviews.
  - c. The written personnel qualification standards established by the third party to assure that its personnel, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)s that the third party accepts for review.
  - d. The documentation (e.g., CVs) to establish that the reviewers of 510(k)s and other involved non-supervisory personnel meet the third party's established criteria for qualified personnel. This includes documentation of education, training, skills, abilities, and experience including specialized education and experience needed for the review of class II devices the third party accepts for review.
  - e. The documentation (e.g., CVs) to establish that the supervisor(s) of 510(k) reviewers has sufficient authority and competence with regard to the third party's established criteria for qualified personnel. This includes documentation of education, training, skills, abilities, and experience including any specialized education and experience needed for review of the class II devices the third party accepts for review.

The third party's management structure, or if the third party uses a contractor for 510(k) reviews, the contractor's management structure. Show the position of the individual(s) providing supervision within the management structure and how that structure provides for the supervision of the reviewers of 510(k)s and other personnel involved in the review process.

## **CERTIFICATION/AGREEMENT STATEMENT**

- 11) A statement, signed by the most responsible individual at the third party firm, certifying/agreeing that:
- a. The third party and its employees (regular or contract) meet its established criteria to ensure freedom from conflicts of interest.

Where the third party uses the services of a contractor for 510(k) reviews, the third party is to include in their signed certification statement that their contractor meets the third party's established criteria for freedom from conflicts of interest.

- b. The third party consents to FDA inspection and copying of all records, correspondence, and other materials relating to any review conducted by the third party under this pilot program, including records on personnel education, training, skills, and experience, all documentation on prevention of conflicts of interest, and the third party's fee schedule and invoices for conducting 510(k) reviews.
- c. The third party will strictly preserve and protect the confidentiality of all information provided by any manufacturer and by FDA.